

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2004/025560

International filing date (day/month/year)
05.08.2004

Priority date (day/month/year)
07.08.2003

International Patent Classification (IPC) or both national classification and IPC
C12N15/63, C07K14/705, C07K16/28, G01N33/50, A61K48/00

Applicant
THE GOVERNMENT OF THE UNITED STATES OF AMERICA...

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
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Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☒ in written format
 - ☒ in computer readable form
 - c. time of filing/furnishing:
 - ☒ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

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Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 55-63

because:

☒ the said international application, or the said claims Nos. 55-63 relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the whole application or for said claims Nos.

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See separate sheet for further details

**WRITTEN OPINION OF THE
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Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-25, 27-42
	No: Claims	43-63
Inventive step (IS)	Yes: Claims	
	No: Claims	1-63
Industrial applicability (IA)	Yes: Claims	1-54
	No: Claims	55-63

2. Citations and explanations

see separate sheet

**WRITTEN OPINION OF THE
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AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2004/025560

IP20 Rec'd PCT/PTO 31 JAN 2006

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

Reference is made to the following document/s/:

- D1: WO 01/07628 A (INCYTE GENOMICS, INC; TANG, Y., TOM; HILLMAN, JENNIFER, L; BANDMAN, OL) 1 February 2001 (2001-02-01)
- D2: ALBERDI E ET AL: "BINDING OF PIGMENT EPITHELIUM-DERIVED FACTOR (PEDF) TO RETINOBLASTOMA CELLS AND CEREBELLAR GRANULE NEURONS" JOURNAL OF BIOLOGICAL CHEMISTRY, AMERICAN SOCIETY OF BIOLOGICAL CHEMISTS, BALTIMORE, MD, US, vol. 274, no. 44, 1999, pages 31605-31612, XP001023972 ISSN: 0021-9258

The present application relates to PEDF-receptor molecules and the DNA sequences coding therefore. The claims cover human, rat and mouse PEDF-R related products, and their application.

D1 discloses nucleic acid and amino acid sequences which are almost identical with the amino acid sequences claimed in the present application. In particular, Seq. ID No. 1 (human cDNA) is identical in 99.842 % with the sequence ID No. 24, Seq. 12 (mouse cDNA) is identical in 77.1% and Seq. 15 (rat cDNA) shares 83,4% identity. 100% identity could be found between Seq. Id No. 9 and Seq. ID No. 3 (human protein). High homology to mouse and rat amino acid sequences are respective. Due to the fact that the scope of most of the claims extends far beyond the specific sequence, the product claims 1-25 and 27-42 lack novelty as required by Article 33(2) PCT. This objection applies although D1 does not disclose that the sequence encodes the PEDF-receptor.

As far as an inventive step is concerned reference is made to D2. D2 concerns the identification of the PEDF receptor and its isolation. The physiological role of the receptor as a neurotrophic receptor is also disclosed. The difference vis à vis the disclosure of the present application relates to the cloning of said receptor. However, the present authority cannot recognize any inventive merit in the provision of the DNA sequence and the

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recombinant PEDF receptor. Starting from the knowledge of D2, a person skilled in art would arrive at the claimed subject-matter by applying standard techniques. Therefore none of the claims can be considered to involve an inventive step (Article 33(3) PCT).

For the assessment of the present claims 55 - 63 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.